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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,087	02/18/2005	Pertti Happonen	06267.0120	5488

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,087	HAPPONEN ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendments and Remarks filed on 03/06/07. Claims 1-5 have been cancelled and claims 13 and 15 have been amended. Accordingly claims 6-15 remain pending.

Claim Rejections - 35 USC § 112

The rejection of claim 15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for asthma, does not reasonably provide enablement for "other respiratory disorders" has been overcome by amendments to claim 15. This said rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aho et al (WO 0001667) in view of Ekström (WO 9964014).

Aho et al teach the compound orazipone and its formulations for treating respiratory diseases, especially asthma. It is disclosed that while budesonide is one of the best medicaments for treating asthma, for patients with steroid-resistant asthma orazipone has shown to be a suitable substitute for budesonide (page 2). Aho does not specifically disclose combining budesonide and orazipone.

Ekström teaches use of a composition comprising formoterol and budesonide for the treatment of asthma by inhalation. Ekström also discloses that for treating asthma formulations comprising a combination of formoterol, budesonide and one or more different active agents would be useful (page 3). Examples show formulations comprising formoterol fumarate dehydrate and budesonide mixed with a carrier such as lactose in a dry powder form micronized to less than 10 micron in size. The devices suitable for delivering the said formulation to the respiratory system include dry powder inhaler, pressurized metered dose inhaler or a nebulizer (see page 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the formulations of Aho et al on orazipone being equivalent to budesonide for treating asthma with formulations and methods of Ekström on combining formoterol and budesonide and optionally other active agents for treating

asthma, with reasonable expectations of successfully treating asthma with a combination of active agents confirmed for their suitability for the said treatment. In other words one of ordinary skill in the art would have concluded from the prior art of record that combining orazipone, formoterol and budesonide would increase chances of recovery significantly.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-17 of U.S. Patent No. 6,201,027 in view of Ekström (WO 9964014).

The obviousness-type double patenting rejection is appropriate, although the conflicting claims are not identical, because the examined claims would have been obvious over the reference claims. Specifically, claims of the instant application recite an inhalation medicament comprising orazipone and a $ß_2$-adrenoreceptor agonist and/or a corticosteroid as a combined preparation, a device for its administration and a method of treating asthma. The reference claims are drawn to a formulation of orazipone and a method of treating asthma. Ekström teaches use of a composition comprising a combination of formoterol and budesonide and optionally other active agents for the treatment of asthma by inhalation. Thus it would have been obvious to one of ordinary skill in the art to have combined the said two or more active agents including orazipone for a successful treatment method.

Response to Arguments

Applicant's arguments filed 03/06/07 have been fully considered but they are not persuasive.

Applicant argues that "Aho et al suggests the use of orazipone in patients who are intolerant to traditional steroid therapy as an alternative to budesonide (bottom of page 4 of remarks). Applicant thus believes that Aho et al's disclosure is a teaching away from proposed combination. While examiner agrees that Aho et al teaches use of orazipone in steroid resistant patients, this is not considered a "teaching away".

Aho et al disclose that 1) corticosteroids are most effective drugs for treating asthma (col. 1, lines 31-33), 2) orazipone is an effective drug for treating or preventing

respiratory disorders such as asthma and COPD (see col. 3, lines 30-33). Ekstrom also teaches that combination of active agents is a suitable method of treating patients. It is disclosed that combining active agents resolves the issue of "poor compliance" because the patient only administers one single dose. Combination of active agents also helps with handling maintenance treatment together with treatment of acute situations (see page 2). Thus sufficient information is provided by one of ordinary skill in the art to easily and safely combine the two active agents for improved therapy.

On the other hand Aho et al are only suggesting that orazipone is useful for those patients that are steroid resistant, however, there is no "teaching away" from either the advantages of treating patients with budesonide or the combination of orazipone and budesonide in patients that are NOT resistant to steroids. One of ordinary skill in the art would clearly be able to distinguish the advantages of such combination for these patients.

Applicant argues that combination of orazipone and budesonide shows superior and synergistic anti-inflammatory effect. This is not contested, however, it would have been obvious to one of ordinary skill in the art. In fact that is the reason combination therapies are used in the field of medicine and are quite common and conventional (see e.g. Ekstrom).

Applicant's arguments regarding the obviousness double patenting rejection are also found not persuasive for the same reasons as stated above. Aho et al teaches use of orazipone in inhalation compositions and Ekstrom teaches combinations of active agents with budesonide. Both agents are taught for treating respiratory disorders such

as asthma and COPD. It then would have been obvious to one of ordinary skill in the art to combine orazipone and budesonide for a combinatory effect.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
May 09, 2007

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